K001147

FEB 1 5 2001

510(k)
Summary
Enhanced Polyethylene Knee Prostheses

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Mary-Catherine Dillon Regulatory Affairs Team Member
Date of Summary Preparation:	November 20, 2000

Device Identification

Proprietary Name:	Enhanced Polyetheylene Knee Prostheses
Common Name:	Knee Prosthesis
Classification Name and Reference:	Knee Joint, Patellofemorotibial, Polymer/Metal/Polymer, Semi-Constrained, Cemented Prosthesis 21 CFR §888.3560

Predicate Device Identification

The features of the subject devices are substantially equivalent to the features of the following Howmedica Osteonics predicate devices: Scorpio CR knee system (tibial inserts and all poly patellar components),and the Duracon knee system (condylar and A/P lipped tibial inserts, and all poly patellar components).

Device Description

The subject devices are identical in design to their counterpart predicate component designs. Only the polyethylene used to manufacture the components will change. This enhanced polyethylene has already received market clearance via 510(k) K990849. The components produced by this method conform to the requirements for Ultra High Molecular Weight Polyethylene (UHMWPE) specified in ASTM F-648, and the FDA guidance document on UHMWPE used in bearing surfaces for orthopedic devices.

Intended Use:

The intended uses of the subject devices are identical to those of the predicate devices.

The specific indications for Scorpio Cruciate (CR) Knee Systems are:

- Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis
- Post-traumatic loss of knee joint configuration and function
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability
- Revision of previous unsuccessful knee replacement or other procedure

The specific indications for Duracon Total Knee System are:

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity
- Revision procedures where other treatments or devices have failed
- Post-traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy
- Irreparable fracture of the knee

Statement of Technological Comparison:

The subject devices are substantially equivalent to the predicate devices in terms of design, indications, contraindications, and material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 15 2001

Ms. Margaret F. Crowe
Regulatory Affairs Consultant
Howmedica Osteonics Corporation
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

Re: K001147
Trade Name: Enhanced Polyethylene Knee Prostheses
Regulatory Class: II
Product Code: JWH
Regulation: 21 CFR 888.3560
Dated: November 20, 2000
Received: November 21, 2000

Dear Ms. Crowe:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Milken

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K001147
Enhanced Polyethylene for Knee Prostheses

Indications for Use:

The intended use for all Enhanced Polyethylene components is identical to their non-Enhanced Polyethylene counterparts.

The specific indications for Scorpio Cruciate (CR) Knee Systems (tibial inserts and all-polyethylene patellar components) are:

- Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis
- Post-traumatic loss of knee joint configuration and function
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability
- Revision of previous unsuccessful knee replacement or other procedure

The specific indications for Duracon Total Knee System (Condylar and A/P lipped tibial inserts, and all-polyethylene patellar components) are:

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity
- Revision procedures where other treatments or devices have failed
- Post-traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy
- Irreparable fracture of the knee

These polyethylene products are intended to be used a part of a cemented total knee system.

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K001147